MDCH Synopsis of Comments for CON Standards Scheduled for 2007 Review Presented to CON Commission March, 13, 2007

COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES (Please refer to 2.15.07 MDCH staff analysis for additional detail – attached)			
All Identified Issues		naiysis for additional deta Recommended	all – attached) Other/Comments
All Identified Issues	Issues Recommended	Course of Action to	Other/Comments
	as Requiring Review	Review Issues	
1. Review volume	Yes		
commitment numbers	res	Potentially refer for SAC discussion	
(actual, projected &		SAC discussion	
thresholds)			
2. Review relocation &	Yes	Potentially refer for	
replacement criteria	100	SAC discussion	
and definitions		0/10/01300331011	
3. Review	Yes	Potentially refer for	
commitment		SAC discussion	
procedures; make			
them similar to MRI &			
PET			
4. Review criteria and	Yes	Potentially refer for	
processes for		SAC discussion	
addressing emerging			
specialty use			
scanners (e.g., dental,			
"mini", portable,			
hybrid)	V ₂ -	Detections	
5. Review pediatric criteria and need for	Yes	Potentially refer for SAC discussion	
specific weighting		SAC discussion	
6. Review use of	Yes	Potentially refer for	
commitments from	100	SAC discussion	
other states		Crite dissassion	
7. Review CT scanner	Yes	Potentially refer for	
use in simulation MRT		SAC discussion	
8. Technical changes	Yes	Review draft language	
in language to be		developed by MDCH	
uniform with other		staff and take action	
CON standards		at completion of SAC	

Recommendation: The Department suggests that the Commission assign responsibility to Department staff to draft technical changes (#8) for appropriate Commission review and public comment. Additionally, the Department recommends that the Commission consider appointing a SAC to bring back recommendations for items 1 through 7 and to ask the SAC to present its final recommendations at the December 2007 meeting. The Department is prepared to assist the Chair and Vice-Chair in drafting a charge to the SAC that is based upon the Commission's determination and decision of the items that are to be included.

Michigan Department of Community Health MEMORANDUM Lansing, MI

DATE: February 15, 2007

TO: Irma Lopez

FROM: Matt Jordan

RE: Summary of Public Hearing Comments on Computed Tomography (CT)

Standards

Note

The information below is only a summary. Please review the Public Hearing folder for a complete transcript of the oral comments and copies of documents provided in written format.

Oral Testimony Summary

Two individuals testified for two facilities/organizations.

Bob Meeker, Spectrum Health: Relocation language of CT scanners should be modified/changed to be more in line with other CON services, such as MRI. This would permit the relocation of individual units as well as the entire CT service, whereas the current CT standards only permit the relocation of the entire service; additional adjustment of standards to allow an underperforming unit to be relocated when operating below the volume threshold; consideration of a dollar amount to distinguish between an upgrade (non-CON action) and a replacement (CON action); consideration of adding a weight to procedures done on special needs and/or pediatric patients; the need for lower volume numbers and requirements for specialty use CT scanners and mini-CT scanners, but while still recognizing a need for some level of regulation on those types of CT scanners.

Steven Szelag, University of Michigan Health System: CT scanner technology is continuing to evolve; the new technology allows for enhanced ways to diagnose disease; while the applications of specialty CT scanners and mini CT scanners is broad, regulation may still be necessary to promote efficient and proper health care and to avoid a rush of machines to the state; special requirements are needed for volumes and use of specialty CT scanners and mini CT scanners; recommends a workgroup or Standard Advisory Committee.

Written Testimony Summary

Four individuals provided written testimony, representing four facilities/organizations.

Caroline Ruddell, Michigan Dental Association: Dental CT scanners should be exempt from CON regulations and the CON Commission should take action to change the current regulations; CON regulations are hindering Michigan citizens' access to the current technology; dental CT scanners have a much lower cost than full body CT scanners and are cheaper than other unregulated pieces of equipment; dental CT scanners replace currently unregulated equipment such as a panoramic x-ray.

Ghabi Kaspo, DDS: Dental CT scanners should be exempt from CON regulations; current regulations on dental CT scanners is hindering access to this important technology; regulating dental CT scanners decreases the quality of care for Michigan residents and forces unnecessary procedures and expenses; CON has never regulated dentistry before and by forcing regulations upon dentists, it is creating delays to access of this important technology.

Ronald Lints, DDS: Dental CT scanners should be exempt from CON regulations; dental CT scanners are significantly different than full body CT scanners, particularly relating to the cost of the equipment; CON does not regulate any other piece of equipment that is as inexpensive as dental CT scanners; Con has never before entered into the realm of dentistry; dental CT scanners are an enhancement upon current products like panoramic x-ray, and not an evolution or use out of a full body CT scanner, which distinguishes it from other specialty CT scanners.

Theodore Freeland, DDS: Dental CT scanners should be exempt from CON regulations; CON has never before regulated dentistry; dental CT scanners are very different from medical CT scanners, particularly in cost of the equipment; dental CT scanners are nearly interchangeable with panoramic x-ray and cephalometric machines, which CON does not currently regulate; dental CT scanning is not replacing other CON covered equipment, but rather replacing currently uncovered equipment.

Email Testimony Summary

Five individuals provided electronic mail testimony, representing five facilities/organizations:

Barbara Jackson, Economic Alliance for Michigan: The current CT Standards language is very imprecise; the modality is continuing to evolve and possibly bringing increased cost and applications; the CT physician commitment process should be strengthened and brought in line with similar provisions in the standards for MRI and PET; volume commitment should be based upon actual utilization, not projected future utilization; supports a deliberate process for specialty use CT scanners, recognizing that different requirements are needed for volume, cost, and quality; CT Standards need to address the use of hybrid machines such as a PET/CT scanner.

Predrag Sukovic, Xoran Technologies: Michigan should carve out an exception in the CT Standards for low radiation dose specialty CT scanners; consider exempting specialty CT scanners from CON regulation, either based upon cost, use, or low radiation output levels; specialty CT scanners such as the MiniCAT provide great benefit to the patient and point of care delivery; low dose radiation machines would benefit Michigan residents in safety and cost, and would free full body CT scanners to do the advanced scanning they were designed for originally.

Stanley Skarli, DeVos Children's Hospital: supports the creation of alternative volume numbers for portable CT scanners; portable CT scanners provide better technology and lower cost for the patient; portable CT scanners reduce risk and cost associated with moving a patient to receive a CT scan; lower volume numbers would allow xenon CT scanning to be done at a lower cost.

Robert Meeker, Spectrum Health: CT Standards have served the state well, but particular provisions need to be reviewed and updated; those areas include clarification of the requirements for relocation, revised definition of replacement, specific acknowledgement of the imaging requirements for pediatric patients, and allowance for new CT technology; relocation of a specific CT scanner versus relocation of an entire service.

Mike Abney, Neurologica: recommends alternative CT equivalents for point of care CT scanners such as bedside scanners; the CereTom scanner is important to Michigan and provides imaging access to recent stroke and TBI patients; the CereTom protects the patient's health by avoiding frequent moves from the ICU to a traditional CT scanner; promoting an annual volume level of around 2000 CT equivalents; or alternatively, an adjustment in the conversion factors for a point of care CT scanner; CereTom scanner is significantly less than traditional CT scanners.

Policy issues to be addressed

Based upon the various testimonies provided, as well as the goals being promoted by MDCH, the CON Policy Section should decide whether to continue with the current CT Standards or to modify the CT Standards. If modifying is chosen, the CON Policy Section should then decide whether a workgroup or a Standard Advisory Committee (SAC) would handle the public discussion and proposed modification. The testimony above indicates that the CT Standards contain a wide breadth of issues to potentially be reviewed, including but not limited to the following: actual commitments, projected commitments, volume threshold, full body CT scanners, specialty and mini CT scanners, dental CT scanners, pediatric patients, and relocation of a CT scanner or a service. Additionally, the CON Program Section has indicated that there are numerous operational and application issues with the current CT Standards that the Section would like to propose to change.